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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,655	11/28/2006	Matthew J. Scanlan	L0461.70156US00	5836

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
06/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,655	SCANLAN ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *180-191* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *180-191* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/3/08; 2/21/07; 12/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restriction

The response filed on 3/19/08 to the restriction requirement of 2/7/08 has been received. Without traverse, Applicant has elected Group II and polypeptides encoded by SEQ ID NO:10.

Claims 180-191 are pending and are currently under consideration.

Specification

The specification is objected to because it contains embedded hyperlinks and/or other form of browser-executable code (see page 2 and throughout Example 1, for example). Applicant is required to delete all embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 180-191 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polypeptides comprising the sequence set-forth in SEQ ID NO:55, **the specification does not reasonably provide enablement for** just any polypeptide comprising just any polypeptide fragment of SEQ ID NO:55 that is at least 8 amino acids in length. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention in manners disclosed in the specification.

Factors to be considered in determining whether undue experimentation is required are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The instant claims are broadly drawn to just any polypeptide comprising just any polypeptide fragment of SEQ ID NO:55 that is at least 8 amino acids in length. This includes polypeptides that are vastly different, both structurally and functionally, from SEQ ID NO:55. Further, this included polypeptides that would not induce the production of antibodies that specifically bind polypeptides comprising SEQ ID NO:55.

The specification discloses polypeptides comprising the sequence set-forth as SEQ ID NO:55. The specification further discloses said polypeptide are to be used to elicit antibodies to a sarcoma-associated antigen (see line 33 on page 6 and pages 17-20, in particular). However, the specification does not provide guidance as to which polypeptides comprising fragments of SEQ ID NO:55 would and would not elicit antibodies to a sarcoma-associated antigen. The specification does not disclose which polypeptides encompassed by the claimed provide epitope binding regions that are exposed on sarcoma-associated antigens.

The prior art of Dumas et al teaches an isolated polypeptide, SEQ ID NO:4557, which comprises a sequence comprising a 40+ amino acid fragment of instant SEQ ID NO:55 (see sequence 35 U.S.C. 102(b) rejection below). However, SEQ ID NO:4557 is only 18.3% identical to instant SEQ ID NO:55 (see sequence comparison below).

One of skill in the art would recognize that polypeptides elicit antibodies that specifically bind epitopes on said polypeptides. One of skill in the art would further recognize that some fragments of sarcoma-associated antigens are not exposed epitopes of sarcoma-associated antigens that would bind antibodies. Further, antibodies elicited by fragments of sarcoma-associated antigens that are not exposed epitopes of sarcoma-associated antigens could not predictably be used as contemplated to elicit antibodies that would bind sarcoma-associated antigens.

Further, the teachings of Dumas et al highlight the unpredictability of using the claimed polypeptides to elicit antibodies to sarcoma-associated antigens. Polypeptides encompassed by the instant claims share a high degree of homology with a fragment of a polypeptide taught by Dumas et al. However, in total, the polypeptide taught by Dumas et al shares low homology with disclosed sarcoma-associated antigens. Therefore, due to the lack of guidance as to which polypeptides encompassed by the claims would elicit antibodies to sarcoma-associated antigens or would elicit antibodies to structurally and functionally different proteins, one of skill in the art would not predict that just any polypeptide encompassed by the claims could be used as contemplated with any predictability of success. Undue experimentation would be required to

determine which polypeptides encompassed by the claims would function as contemplated.

One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to just any polypeptide comprising just any polypeptide fragment of SEQ ID NO:55 that is at least 8 amino acids in length, and Applicant has not enabled just any polypeptide comprising just any polypeptide fragment of SEQ ID NO:55 that is at least 8 amino acids in length because it has not been shown that just any polypeptide comprising just any polypeptide fragment of SEQ ID NO:55 that is at least 8 amino acids in length would elicit antibodies that bind sarcoma associated antigens.

In view of the teachings above and the lack of guidance, workable examples and or exemplification in the specification, it would require undue experimentation by one of skill in the art to determine with any predictability, which polypeptides encompassed by the claims would function as contemplated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 180-182 and 189-191 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumas et al (EP 1 033 401 A2; 9/6/00).

Claim 180 is drawn to an isolated polypeptide with a sequence as set forth as SEQ ID NO:55 or a fragment thereof that is at least 8 amino acids in length. Claim 181 is drawn to the isolated polypeptide of claim 180, wherein the fragment is at least 9-100 amino acids in length. Claim 182 is drawn to a composition comprising the isolated polypeptide of claim 180 or 181 and a pharmaceutically acceptable carrier. Claim 189 is drawn to a kit comprising one or more sarcoma-associated antigens with a sequence set-forth as SEQ ID NO:55 or a fragment thereof that is at least 8 amino acids in length and instructions for use of the sarcoma-associated antigens in detection of antibodies in the biological sample. Claim 190 is drawn to the kit of claim 189, wherein the fragment is at least 9-100 amino acids in length. Claim 191 is drawn to the kit of claim 189 or 190, wherein the sarcoma-associated antigen is bound to a substrate.

It is noted that the "instructions" of claim 189 are viewed as intended use and are not given patentable weight and are not limitations to the claim. Statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)).

Dumas et al teaches an isolated polypeptide, SEQ ID NO:4557, with a sequence set forth as a fragment of instant SEQ ID NO:55, wherein the fragment is at least 40 amino acids in length (see sequence comparison below). Dumas et al further teaches said polypeptide is an "incomplete polypeptide sequence" that includes a signal peptide (see paragraph 103, in particular). Dumas et al further teaches said isolated

polypeptide in growth medium (see paragraph 163, in particular). Said growth medium is a pharmaceutically acceptable carrier and a substrate to which said isolated polypeptide is bound. Dumas et al further teaches using said isolated polypeptide, which comprises a signal peptide, to produce antibodies (paragraph 352, in particular).

Comparison of SEQ ID NO:4557 with instant SEQ ID NO:55:

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Query Match             18.3%;  Score 247;  DB 3;  Length 51;
  Best Local Similarity   96.0%;  Pred. No. 7.1e-18;
  Matches   48;  Conservative    0;  Mismatches    2;  Indels    0;  Gaps
0;

Qy        184 MMQMFGLGAISLILVCLPIYCRSLFWRSEPADDLQRQDNRVVTGLKKQRR 233
              ||||  ||||||||||||||||||||||||||||||||||||||||||||
Db          1 MMQMXXLGAISLILVCLPIYCRSLFWRSEPADDLQRQDNRVVTGLKKQRR 50
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Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Examiner, Art Unit 1642